K073380

510(k) SUMMARY

SUBMITTER:

Sorin Group Italia S.r.l.
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FEB 29 2008

CONTACT PERSON:

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DATE PREPARED:

November 30, 2007

DEVICE TRADE NAME:

SYNTHESIS Ph.I.S.I.O.: Adult Membrane Oxygenator With Integrated Arterial Filter and Hardshell Venous/Cardiotomy Reservoir with Phosphorylcholine (Ph.I.S.I.O.) coating

SYNTHESIS C Ph.I.S.I.O.: Adult Membrane Oxygenator With Integrated Arterial Filter and Softshell Venous Reservoir with Phosphorylcholine (Ph.I.S.I.O.) coating

SYNTHESIS M Ph.I.S.I.O.: Adult Membrane Oxygenator With Integrated Arterial Filter with Phosphoryulcholine (Ph.I.S.I.O.) Coating

SYNTHESIS R Ph.I.S.I.O: Hardshell Venous and Cardiotomy Reservoir with Phosphorylcholine (Ph:I.S.I.O.) Coating

COMMON NAME:

Hollow Fiber Membrane Oxygenator/Integrated Arterial Filter/Reservoir

Hollow Fiber Membrane Oxygenator/Softshell Venous Reservoir/Integrated Arterial Filter

Hollow Fiber Membrane Oxygenator/Integrated Arterial Filter

Hollow Fiber Membrane Oxygenator/Integrated Arterial Filter

Softshell Venous Reservoir

CLASSIFICATION NAME:

Cardiopulmonary Bypass Oxygenator/ Cardiopulmonary Bypass Heat Exchanger/ Cardiopulmonary Bypass Blood Reservoir/ Cardiopulmonary Bypass Defoamer/ Cardiopulmonary Bypass Arterial Line Blood Filter

PREDICATE DEVICES:

SYNTHESIS MIMESYS Adult Membrane Oxygenator with Integrated Arterial Filter and Hardshell Venous/Cardiotomy Reservoir Mimesys treated (Phosphorylcholine coating hereinafter called PC coating) (K031233)

SYNTHESIS C MIMESYS: Adult Membrane Oxygenator With Integrated Arterial Filter and Softshell Venous Reservoir Mimesys Treated (Phosphorylcholine coating hereinafter called PC coating)

SYNTHESIS M MIMESYS Adult Membrane Oxygenator with Integrated Arterial Filter Mimesys treated (Phosphorylcholine coating hereinafter called PC coating)

SYNTHESIS R MIMESYS: Hardshell Venous and Cardiotomy Reservoir Mimesys treated (Phosphorylcholine coating hereinafter called PC coating)

DEVICE DESCRIPTION:

SYNTHESIS Ph.I.S.I.O. Adult Membrane Oxygenator With Integrated Arterial Filter and Hardshell Venous/Cardiotomy Reservoir with Phosphorylcholine (Ph.I.S.I.O.) hereinafter called the SYNTHESIS Ph.I.S.I.O., is a high efficiency microporous hollow fiber membrane oxygenator integrated with a heat exchanger and an arterial filter and connected to a hardshell cardiotomy venous reservoir. The SYNTHESIS Ph.I.S.I.O. (and other modified versions) have been modified for the change in coating material applied to the arterial filter and for some ergonomic and cosmetic enhancements. The arterial filter of the device is now coated with a new coating containing the same phosphorylcholine monomer currently used for coating of the device. No modifcation to the intended use has been made as result of the modifications.

INDICATION FOR USE:

SYNTHESIS Ph.I.S.I.O. is a sterile, nonpyrogenic device intended for use in cardiopulmonary bypass circuits as substitute for the lungs (transfer of oxygen and removal of carbon dioxide), to control the arterial/venous temperature, and as venous blood reservoir and filter element to eliminate gas emboli and remove blood component aggregates larger than 40µm. SYNTHESIS Ph.I.S.I.O. is an adult oxygenator intended for use in operations on adult patients. SYNTHESIS Ph.I.S.I.O. must not be used for longer than 6 hours. Contact with blood for longer periods is inadvisable.

TECHNOLOGICAL CHARACTERISTICS:

The SYNTHESIS Ph.I.S.I.O. Adult Membrane Oxygenator with Integrated Arterial Filter and Hardshell Venous/Reservoir with Phopsporilcholine (Ph.I.S.I.O.) coating, is essentially identical to the SYNTHESIS MIMESYS predicate device with respect to operating principles, control mechanisms and biocompatibility of the new phosphorylcholine coating. The major modification made to the SYNTHESIS Ph.I.S.I.O. (and other modified versions) is the application of the new phoshorylcholine coating on the integrated arterial filter. No modification has been made to the current phosphorylcholine coating already present on the entire oxygenating module with heat exchanger and hardshell venous reservoir (except the filtering media of the reservoir) and softshell venous reservoir. The hardshell venous reservoir present in both SYNTHESIS Ph.I.S.I.O. and SYNTHESIS MIMESYS predicate device share the same technological characteristics, operating principles and materials except for some ergonomic modifications to ensure a more effective use.

The oxygenator is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only.

BIOCOMPATIBILITY TEST RESULTS:

A complete battery of tests were carried out in accordance with the requirements of ISO 10993-1:1995 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility

testing on the raw materials. Testing was performed on the SYNTHESIS Ph.I.S.I.O. (accelerated aging). The device was tested for Hemolysis, Hemocompatibility (including thrombosis and blood compatibility study with human blood), Cytotoxicity, Irritation, Acute Systemic Toxicity and Mutagenicity. Sterility, Pyrogenicity. ETO residuals and package integrity testing were also conducted. The results of the testing met established specifications.

***IN VITRO* TEST RESULTS**:

In vitro testing were carried out in accordance with the requirements of "Guidance for Cardiopulmonary Bypass Arterial line Blood Filter 510(k) Submission" Final Guidance for industry and FDA issued on November 29, 2000; "Guidance for Blood Extracorporeal Blood Circuit Defoamer 510(k) Submission" Final Guidance for Industry and FDA issued on November 29, 2000 - ISO 15675:2001 "Cardiovascular implants and artificial organs – Cardiopulmonary bypass systems – Arterial line blood filters" and ISO 15674:2001 – "Cardiovascular implants and artificial organs – Hardshell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags", where applicable for providing the data necessary to demonstrate both the substantial equivalence with the predicate device and also compliant with safety and effectiveness requirements. The device was aged up to 3 (+1 year considered as a worst case) was tested for: Arterial Filter Characterization (including Priming Efficiency, Pressure Drop, Hemolysis/Cell Depletion & Visual Inspection, Filtration Efficiency, Air Handling, Structural Integrity, Pressure Integrity); Stability of Coating (including Leaching of Coating, Flaking of Coating, Cracking of Coating); Hardshell Cardiotomy/Venous Reservoir Characterization (including: Breakthrough Time and Volume, Graduated Scale Accuracy, Hemolysis/Cell Depletion & Visual Inspection, Filtration Efficiency). The results of these tests met established specifications. For comparative purposes, the same testing, when applicable, has been conducted also on the SYNTHESIS MIMESYS predicate device. This 510(k) crosses reference performance data previously submitted in the SYNTHESIS MIMESYS 510k (K031233) for the gas transfer studies, operating blood volumes, heat exchanger performance evaluation, uniformity of PC coating on coated surfaces, softshell venous reservoir characterization (micorembolic activity and filtration efficiency), residual blood volume, defoaming capacity and breakthroughtime and volume of the cardiotomy section as the above mentioned aspects are not affected by the modification. The shipping carton passed the basic testing and was still capable of providing adequate protection for further handling.

The results of the study showed the device characteristics between SYNTHESIS Ph.I.S.I.O. and SYNTHESIS MIMESYS were comparable.

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the SYNTHESIS Ph.I.S.I.O. (and other modified versions) devices perform in a manner substantially equivalent to the predicate devices. Biocompatibility studies demonstrate that the new phosphorylcholine-based coating is biocompatible and functional tests demonstrate that its performance is equivalent to the SYNTHESIS MIMESYS predicate device, according to its intended use. Additional testing has demonstrated the effectiveness of production techniques to assure that the oxygenator is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 29 2008

Sorin Group Italia, S.r.l.
c/o Mr. Barry Sall
Principal Consultant
Parexel Consulting
200 West Street
West Street, Waltham, MA 02451-1163

Re: K073380
Synthesis Ph.I.S.I.O. Adult Membrane Oxygenator with Integrated Arterial Filter and Hardshell Venous/Cardiotomy Reservoir with Phosphorylcholine (Ph.I.S.I.O.) Coating
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary bypass oxygenators
Regulatory Class: Class II
Product Code: DTZ
Dated: November 30, 2007
Received: December 3, 2007

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K073380

Device Name: Synthesis Ph.I.S.I.O. Adult Membrane Oxygenator with Integrated Arterial Filter and Hardshell Venous/Cardiotomy Reservoir with Phosphorylcholine (Ph.I.S.I.O.) Coating

Indications For Use:

Synthesis Ph.I.S.I.O. is intended for use in cardiopulmonary bypass circuits as substitute for the lungs (transfer of oxygen and removal of carbon dioxide), to control the arterial/venous temperature, and as venous blood reservoir and filter element to eliminate gas emboli and remove blood component aggregates larger than 40 µm. Synthesis Ph.I.S.I.O. is an adult oxygenator intended for use in operations on adult patients. Synthesis Ph.I.S.I.O. must not be used for longer than 6 hours. Contact with blood for longer periods is inadvisable.

Synthesis M Ph.I.S.I.O. Adult Membrane Oxygenator with Integrated Arterial Filter with Phosphorylcholine (Ph.I.S.I.O.) Coating

Indications For Use:

Synthesis M Ph.I.S.I.O. is intended for use in cardiopulmonary bypass circuits as substitute for the lungs (transfer of oxygen and removal of carbon dioxide), to control the arterial/venous temperature, and as filter element to eliminate gas emboli and remove blood component aggregates larger than 40 µm. Synthesis M Ph.I.S.I.O. is an adult oxygenator intended for use in operations on adult patients. Synthesis M Ph.I.S.I.O. must not be used for longer than 6 hours. Contact with blood for longer periods is inadvisable.

Synthesis R Ph.I.S.I.O. Hardshell Venous/Cardiotomy Reservoir with Phosphorycholine (Ph.I.S.I.O.) Coating

Indications For Use:

Synthesis R Ph.I.S.I.O. has been specifically designed for cardiovascular procedures requiring cardiopulmonary by-pass. It collects venous blood and it defoams, filters and stores the blood from the operating field through thoracic, intracardiac and general suction. Synthesis R Ph.I.S.I.O. can be used postoperatively for chest drainage. It is suggested not to use Synthesis R Ph.I.S.I.O. for more than 6 hours.

Synthesis C Ph.I.S.I.O. Adult Membrane Oxygenator with Integrated Arterial Filter and Softshell Venous Reservoir with Phosphorylcholine (Ph.I.S.I.O.) Coating

Indications For Use:

Synthesis C Ph.I.S.I.O. is intended for use in cardiopulmonary bypass circuits as substitute for the lungs (transfer of oxygen and removal of carbon dioxide), to control the arterial/venous temperature, and as venous blood reservoir and filter element to eliminate gas emboli and remove blood component aggregates larger than 40 µm. Synthesis C Ph.I.S.I.O. is an adult oxygenator intended for use in operations on adult patients. Synthesis C Ph.I.S.I.O. must not be used for longer than 6 hours. Contact with blood for longer periods is inadvisable.

Prescription Use __X__ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vellucci

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073380